

### **REMARKS**

Claims 23 and 28-32 are in the application. Claims 1-22, 24-27 have been canceled. Claims 28-32 are new.

All composition claims have been cancelled. Method claim 23 has been amended to recite the formula limitations of claim 1. Claims 28-32 have been added to depend from claims 23, support for which can be found in canceled claims 1-22.

Claim 23 has also been amended to incorporate a water washing step in the preparation of the phytase-treated soy protein, support for which can be found in canceled claims 20 and 21.

Claim 23 has also been amended to include a minimum lipid concentration of 2.0%, support for which can be found in Applicants' specification at page 4, Table 1.

Claim 23 has also been amended to include a minimum 0.7% concentration of phytase-treated, water-washed, soy protein, support for which can be found in Applicants' specification at page 4, Table 1.

Claim 23 has also been amended to include a stool softening limitation as characterized by a reduced mean rank stool consistency as compared to a control soy formula without water-washed, phytase treated soy. Support for this amendment can be found in Applicants' specification at page 19, Table 3.4.

### **Examiner Interview**

Applicants' undersigned attorney gratefully acknowledges the personal interview granted by Examiner Helen Pratt on July 25, 2007 at the USPTO, during which the pending prior art rejections and cited references, as well as the current<sup>112</sup> rejection, were discussed. Sandra Weida and William Winter, attorneys for

Applicants, participated in the interview.

Discussions during the interview included proposed amendments for consideration in overcoming the prior art rejections as well as the pending Rule 112 rejection. Applicants' attorneys emphasized the data as set forth in the specification showing unexpected stool softening benefits to further support patentability.

It was agreed that Applicants would cancel the composition claims and amend the remaining method claims to include water-washing limitations for the phytase-treated soy component, and to also include a stool softening limitation.

### **112 Rejection**

Claim 1 has been rejected under 35 USC 112, second paragraph, as being indefinite for reciting a calcium to lipid ratio without also reciting a minimum lipid concentration.

Claim 1 has now been cancelled and its limitations subsequently incorporated into claim 23. However, claim 23 has also been amended to include a minimum lipid concentration of 2.0%, thus avoiding a transfer of the 112 rejection from claim 1 to claims 23.

Applicants submit that the remaining claims are now in compliance with the definiteness requirements of 35 USC 112, second paragraph.

### **Art Rejections**

Claims 1-8, 11-19, and 22-27 have been rejected under 35 USC 103(a) as being unpatentable over Lien et al. (US 2004/0062849) in view of Thomas (US 6,313,272) and Rangavajhyala et al. and Lasekan (US 2004/0062820) and Quinlan et al. Applicants traverse this rejection as it would apply to the remaining amended claims.

Claims 9, 10, 20, and 21 have also been rejected under 35 USC 103(a) as being unpatentable over the above-cited references, and further in view of Simell (EP 0380343) and Han (J. Agric. Food Chem., pages 259-262). These claims have now been cancelled, thus obviating this particular rejection.

The applied prior art references from the May 18, 2007 Office Action are listed in the following table.

	Soy protein	Soy treatment: Phytase + water washing	Formula w/ low phytate levels	Stool softening disclosed	Infant formulas disclosed	Infant Formula Ca: Lipid ratio
Claims 23, 26	Phytase treated	Yes -- claims 32, 33, 38, 39	≤ 0.3% of soy protein	Yes	Yes	0.002-0.02
Thomas US 6,313,273	Phytase treated	--	--	--	Yes	Ca - yes Lipid 2-4.5%
Simell EP 0380343	Phytase treated	Yes	--	--	--	No
Lien US2004- 0062849	-Soy hydrolysate -Phytase treatment disclosed	--	< 100mg/L or <0.01% of formula	--	Yes	0.19
Rangavajhyal US 6,808,736	Soy hydrolysate	--	--	--	Yes	Ca - yes Lipid 1-10%
Han	Soy hydrolysate	--	No	--	--	No
Lasekan US2004- 0062820	Soy and other proteins	--	No	--	Yes	0.014
Quinlan et al.	No	--	No	--	Yes	No

Applicants submit that none of the prior art references disclose or suggest the use of a soy-based infant formula to soften stools. Applicants found that phytase treated soy could be used to soften infant stools even when the infant formula is calcium fortified. It is known that calcium fortification can harden infant stools, as can soy-based infant formulas, but it was not known that the use of a phytase-treated soy protein could be used to off-set such hardening and actually soften stools.

Applicants submit that Quinlan et al. actually teaches away from the claimed method by disclosing that the combination of calcium and lipids from infant formulas, when excreted as fatty acid soaps, contribute to stool hardening (see Quinlan et al., abstract). In the claimed method, however, the formula may contain high levels of both ingredients and actually soften rather than harden infant stools.

Applicants acknowledge that soy infant formulas with reduced phytic acid concentrations are known. Indeed, both Lien and Simell disclose many different methods of reducing phytate levels in soy proteins, including the use of anion exchange resins, water washing methods, phytase treatment methods, pH based precipitations, and so forth.

Applicants have found, however, that phytase treated soy in an infant formula softens infant stools, unlike either conventional soy protein infant formulas or infant formulas with soy protein treated with anion exchange resins to reduce phytic acid levels (see Applicants Specification at page 19, lines 15-27).

Applicants found, specifically, that phytase treatment followed by water washing produced a soy protein that softened infant stools, even in the presence of lipids and enriched calcium concentrations. Upon entry of the amendments presented herein, all claims are now limited by a water-washing step.

Among the cited references, however, Simell discloses phytase treatment followed by water washing (see page 8, lines 35-50). Nonetheless, since Simell fails to disclose the use of the phytase/water washed soy proteins in an infant formula to soften infant stools, and none of the other references disclose a similar outcome, one of ordinary skill in the art would not have found it obvious to use Simell's protein in an infant formula to soften stools.

One of ordinary skill in the art would, therefore, would not find any reason to try a soy-based infant formula to soften stools, since it is well known that such formulas typically have the opposite effect. And even if the claimed method was obvious to

try, which Applicants maintain it is not, the stool softening benefits arising therefrom would not have been expected by one of ordinary skill in the art.

To further emphasize these unexpected stool softening benefits as further support for patentability of the claims, Applicants' have amended all claims to include a stool softening limitation as characterized by a reduction in mean rank stool consistency.

### **Conclusion**

In view of the amendments presented and the foregoing remarks, Applicants respectfully request reconsideration of this application, withdrawal of the current rejections, and allowance of claims 23 and 28-39.

Respectfully submitted,

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